

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant:	Peter Wernet	Confirmation No.:	5815
Serial No.:	10/758,644	Art Unit:	1633
Filed:	January 15, 2004	Examiner:	Quang Nguyen
Customer No.:	21559		
Title:	HUMAN CORD BLOOD DERIVED UNRESTRICTED SOMATIC STEM CELLS (USSC)		

APPLICATION FOR PATENT TERM ADJUSTMENT UNDER 37 C.F.R. § 1.705

In response to the Determination of Patent Term Adjustment under 35 U.S.C. § 154(b) mailed with the Notice of Allowance on December 3, 2008, in connection with the above-captioned patent application, Applicant hereby requests reconsideration of the patent term adjustment.

Applicant submits that the correct patent term adjustment should be 528 days, not 0 days as shown in the Patent Term Adjustment History on the PAIR system (Exhibit I).

## Background Law and Rules

35 U.S.C. § 154(b)(1)(A) states:

Subject to the limitations under paragraph (2), if the issue of an original patent is delayed due to the failure of the Patent and Trademark Office to-

(i) provide at least one of the notifications under section 132 of this title or a notice of allowance under section 151 of this title not later than 14 months after-

the date on which an application was filed under section 111(a) of this title; or

\* \* \*

(ii) respond to a reply under section 132, or to an appeal taken under section 134, within 4 months after the date on which the reply was filed or the appeal was taken;

\* \* \*

(iv) issue a patent within 4 months after the date on which the issue fee was paid under section 151 and all outstanding requirements were satisfied, the term of the patent shall be extended 1 day for each day after the end of the period specified in clause (i), (ii), (iii), or (iv), as the case may be, until the action described in such clause is taken.

Corresponding provisions are found in 37 C.F.R. §§ 1.702(a)(1), (2), and (4), and in 1.703(a)(1) and (4). Applicant refers to Office delay under 35 U.S.C. § 154(b)(1)(A), and the corresponding rules, as “A delay.”

35 U.S.C. § 154(b)(1)(B) states:

Subject to the limitations under paragraph (2), if the issue of an original patent is delayed due to the failure of the United States Patent and Trademark Office to issue a patent within 3 years after the actual filing date of the application in the United States,

\* \* \*

the term of the patent shall be extended 1 day for each day after the

end of that 3-year period until the patent is issued.

Corresponding provisions are found in 37 C.F.R. §§ 1.702(b) and 1.703(b). Applicant refers to Office delay under 35 U.S.C. § 154(b)(1)(B), and the corresponding rules, as “B delay.”

35 U.S.C. § 154(b)(2)(A) states (emphasis added):

**To the extent that periods of delay attributable to grounds specified in paragraph (1) overlap**, the period of any adjustment granted under this subsection shall not exceed the actual number of days the issuance of the patent was delayed.

A corresponding provision is found in 37 C.F.R. § 1.703(f).

The Office has explained its interpretation of the “overlap” provisions of 35 U.S.C. § 154(b)(2)(A) and 37 C.F.R. § 1.703(f) as follows (emphasis added):

[T]he Office has consistently taken the position that if an application is entitled to an adjustment under the three-year pendency provision of 35 U.S.C. 154(b)(1)(B), **the entire period during which the application was pending before the Office** (except for periods excluded under 35 U.S.C. 154 (b)(1)(B)(i)-(iii)), and not just the period beginning three years after the actual filing date of the application, **is the relevant period under 35 U.S.C. 154 (b)(1)(B) in determining whether periods of delay “overlap” under 35 U.S.C. 154(b)(2)(A).**

Explanation of 37 CFR 1.703(f) and of the United States Patent and Trademark Office

Interpretation of 35 U.S.C. 154(b)(2)(A), 69 Fed. Reg. 34283, 34283 (Jun. 21, 2004). However,

the Office’s interpretation was recently rejected by the U.S. District Court for the District of

Columbia, which stated (emphasis added in bold; original emphasis in italics):

The operative question under 35 U.S.C. § 154(b)(2)(A) is whether “periods of delay attributable to grounds specified in paragraph (1) overlap.” **The only way that periods of time can “overlap” is if they occur on the same day. If an “A delay” occurs on one calendar day and a “B delay” occurs on another, they do not overlap, and § 154(b)(2)(A) does not limit the extension to one day.** Recognizing this, the PTO defends its interpretation as essentially running the “period of delay” under sub-section (B) from

the filing date of the patent application, such that a period of “B delay” *always overlaps* with any periods of “A delay” for the purposes of applying § 154(b)(2)(A).

**The problem with the PTO’s construction is that it considers the application *delayed* under § 154(b)(1)(B) during the period *before it has been delayed*. That construction cannot be squared with the language of § 154(b)(1)(B), which applies “if the issue of an original patent is *delayed* due to the failure of the United States Patent and Trademark Office to issue a patent within 3 years.” (Emphasis added.) “B delay” begins when the PTO has failed to issue a patent within three years, not before.**

Wyeth v. Dudas, No. 07-1492 (JR), 2008 U.S. Dist. LEXIS 76063, at \*3 (D.D.C. Sep. 30, 2008).

Accordingly, Applicant submits that, where A delay occurs entirely before the three-year date, and thus does not overlap the period of B delay, the periods of A delay and B delay are not to be considered overlapping under § 154(b)(2)(A), but rather must be added together to determine the overall Office delay.

#### Patent Term Adjustment for the ‘644 Application

The ‘644 application was filed pursuant to 35 U.S.C. § 111(a) on January 15, 2004, and the first Restriction Requirement was mailed by the Office on September 6, 2005, which is 175 days past the 14-month date of March 15, 2004. Thus, at present, the A delay is 175 days. This result is consistent with the Office’s determination as shown in Exhibit I.

Likewise, based on an analysis of 37 C.F.R. § 1.704, Applicant does not dispute the Office’s calculation that the total Applicant delay is 334 days.

The Office did not show a calculation of the period of B delay in Exhibit I. Under 37 C.F.R. §§ 1.702(b) and 1.703(b), the time interval between the date that is three years from the filing date of the application and the mailing of a Notice of Allowance, excluding those periods

set forth in 37 C.F.R. §§ 1.702(b)(1)-(5) and 37 C.F.R. §§ 1.703(b)(1)-(4), counts as B delay. In this case, the three-year date was January 15, 2007, and the Notice of Allowance was mailed on December 3, 2008, or 687 days later; a Request for Continued Examination was not filed in this application. Accordingly, the period of B delay is 687 days.

Under Wyeth, as discussed above, when the periods of A delay and B delay do not overlap, Applicant is entitled to both periods of delay. Here, the period of A delay terminated on September 6, 2005, while the period of B delay began on January 15, 2007, and ran until December 3, 2008. Accordingly, the periods of A delay and B delay are non-overlapping, and Applicant is entitled, under U.S.C. § 154(b)(2)(A) and 37 C.F.R. § 1.703(f), to the sum of these periods in the patent term adjustment calculation.

Applicant concludes that the Office delay associated with the '644 application is 175 days + 687 days = 862 days, while the Applicant delay is 334 days. Thus, the '644 application is entitled to a total of 862 days – 334 days = 528 days of patent term adjustment under 37 C.F.R. § 1.703. Applicant requests that the patent term adjustment determination be corrected accordingly.

The '644 application is not subject to a Terminal Disclaimer.

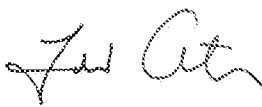
CONCLUSION

Applicant submits that the current patent term adjustment should be 528 days and hereby requests reconsideration of the patent term adjustment.

Please charge \$200.00 to Deposit Account No. 03-2095 in payment of the fee set forth in 37 C.F.R. § 1.18(e). If there are any additional charges or any credits, please apply them to Deposit Account No. 03-2095.

Respectfully submitted,

Date: 28 January 2009

 Todd Armstrong, Ph.D.  
Reg. No. 54,590

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for Paul T. Clark  
Reg. No. 30,162

Clark & Elbing LLP  
101 Federal Street  
Boston, MA 02110  
Telephone: 617-428-0200  
Facsimile: 617-428-7045

# Exhibit 1

## Patent Information

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## Recorded Patent Application Information Retrieval

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10/769,444 HUMAN CORD BLOOD DERIVED UNRESTRICTED SOMATO STEM CELLS (USC)

### Patent Term Adjustment

Filing or 371(c) Date:	01-15-2004	USPTO Delay (PTO) Delay (days):	175
Issue Date of Patent:		Three Years:	-
Pre-Issue Petitions (days):	+0	Applicant Delay (APPL) Delay (days):	324
Post-Issue Petitions (days):	+0	Total Patent Term Adjustment (days):	0
USPTO Adjustment (days):	+0	Explanation Of Calculation:	

### Patent Term Adjustment History

Date	Contents Description	PTO(Days)	APPL(Days)
12-03-2008	Hall Notice of Allowance		
11-26-2008	Notice of Allowance Data Verification Completed		
11-26-2008	Case Docketed to Examiner in GAU		
11-26-2008	Document Verification		
11-24-2008	Examiner's Amendment Communication		
11-18-2008	Examiner Interview Summary Record (PTOL - 413)		
06-16-2008	Information Disclosure Statement considered		
11-13-2008	Date Forwarded to Examiner		
10-20-2008	Amendment after Final Rejection		19
10-20-2008	Request for Extension of Time - Granted		+
06-16-2008	Reference capture on IDS		+
06-16-2008	Information Disclosure Statement (IDS) Filed		70
07-03-2008	Electronic Review		+
07-01-2008	Email Notification		+
07-01-2008	Hall Final Rejection (PTOL - 326)		+
06-16-2008	Information Disclosure Statement (IDS) Filed		+
06-22-2008	Final Rejection		+
04-26-2008	Date Forwarded to Examiner		+
04-07-2008	Response after Non-Final Action		+
04-07-2008	Request for Extension of Time - Granted		59
11-10-2007	Electronic Review		+
11-08-2007	Email Notification		+
11-08-2007	Hall Non-Final Rejection		+
11-05-2007	Non-Final Rejection		+
10-24-2007	Affidavit(s) (Rule 131 or 132) or Exhibit(s) Received		
11-02-2007	Date Forwarded to Examiner		
10-24-2007	Amendment after Final Rejection		
11-01-2007	Email Notification		
11-01-2007	Hall Examiner Interview Summary (PTOL - 413)		
03-08-2007	Examiner Interview Summary Record (PTOL - 413)		
08-01-2007	Hall Final Rejection (PTOL - 326)		
07-27-2007	Final Rejection		
06-27-2007	Information Disclosure Statement considered		
06-27-2007	Information Disclosure Statement (IDS) Filed		
06-03-2007	Date Forwarded to Examiner		
05-16-2007	Response after Non-Final Action		92
05-16-2007	Request for Extension of Time - Granted		+
05-04-2007	Hall Examiner Interview Summary (PTOL - 413)		+
03-08-2007	Examiner Interview Summary Record (PTOL - 413)		+
11-13-2006	Hall Non-Final Rejection		+
11-13-2006	Non-Final Rejection		+
09-09-2006	Date Forwarded to Examiner		
08-18-2006	Response after Non-Final Action		
07-31-2006	Hall Miscellaneous Communication to Applicant		
07-24-2006	Miscellaneous Action with SSP		
05-22-2006	Information Disclosure Statement considered		
05-22-2006	Information Disclosure Statement (IDS) Filed		
05-22-2006	Information Disclosure Statement (IDS) Filed		
05-02-2006	New or Additional Drawing Filed		
05-02-2006	Affidavit(s) (Rule 131 or 132) or Exhibit(s) Received		
05-09-2006	Date Forwarded to Examiner		
05-02-2006	Response after Non-Final Action		
05-02-2006	Request for Extension of Time - Granted		94
10-28-2005	Hall Non-Final Rejection		+
10-27-2005	Non-Final Rejection		+
10-18-2005	Date Forwarded to Examiner		
10-11-2005	Response to Election / Restriction Filed		
09-06-2005	Hall Restriction Requirement		
09-01-2005	Requirement for Restriction / Election	175	+
01-15-2004	Information Disclosure Statement considered		+
06-28-2005	Case Docketed to Examiner in GAU		+
04-16-2005	IPW TSS Processing by Tech Center Complete		+
04-16-2005	Case Docketed to Examiner in GAU		+
01-15-2004	Preliminary Amendment		+
01-15-2004	Reference capture on IDS		+
01-15-2004	Information Disclosure Statement (IDS) Filed		+
01-15-2004	Information Disclosure Statement (IDS) Filed		+
03-22-2005	Application Return from OIPE		+
03-22-2005	Application Return TO OIPE		+
03-21-2005	Application Dispatched from OIPE		+
03-22-2005	Application Is Now Complete		+
03-03-2005	Additional Application Filing Fees		+
03-03-2005	Applicant has submitted new drawings to correct Corrected Papers problems		+
03-03-2005	Applicant has submitted a new specification to correct Corrected Papers problems		+
08-23-2004	Additional Application Filing Fees		+
08-23-2004	A statement by one or more inventors satisfying the requirement under 35 USC 115, Oath of the Applicant		+
08-23-2004	Applicant has submitted new drawings to correct Corrected Papers problems		+
08-23-2004	Applicant has submitted a new specification to correct Corrected Papers problems		+
01-03-2005	Notice Halted-Application Incomplete-Filing Date Assigned		+
03-04-2004	Cleared by OIPE CSR		+
02-03-2004	CRF Is Good Technically / Entered Into Database		+
01-28-2004	IPW Scan & PACR Auto Security Review		+
01-15-2004	CRF Disk Has Been Received by Preexam / Group / PCT		+
01-15-2004	Initial Exam Team on		+

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